

IV. Remarks

A. §112, 2nd ¶

Claims 6-14 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the subject matter. The Examiner contends that claim 6 is vague and indefinite for recitation of non toxic immunogen. The Examiner further contends that intended mutagen is not defined. Specifically, the Examiner queries whether SDS is intended. Further the Examiner rejects the claims on indefinite ground for recitation of the phrase "about." Applicants respectfully request reconsideration in light of this response.

First, as the Federal Circuit has explained, the second paragraph of § 112 contains two requirements: "first, [the claim] must set forth what 'the applicant regards as his invention,' and second, it must do so with sufficient particularity and distinctness, i.e., the claim must be sufficiently 'definite.'" *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1377, 55 USPQ2d 1279, 1282 (Fed. Cir. 2000). In determining whether the claim is sufficiently definite, the courts must analyze whether "one skilled in the art would understand the bounds of the claim when read in light of the specification." *Personalized Media Communications, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705, 48 USPQ2d 1880, 1888 (Fed. Cir. 1998). Here, "non-toxic mutagens" are exemplified on page 2, lines 29-34. One skilled in the art would be able to envision all comparable non-toxic mutagens from the example given. Accordingly, the scope of the phrase "non-toxic mutagen" is not limited to the example given, but encompasses what one of ordinary skill in the art would classify as a non-toxic mutagen. Accordingly, Applicants

respectfully request reconsideration of the rejection.

Second, the term about is rendered definite in the present application when applying the standards announced in the case of *Eiselstein v. Frank*, 34 USPQ2d 1467 (Fed. Cir. 1995). The case concerned an interference priority determination, but is applicable in its discussion of the use of “about” around a numerical range. Applicants in the *Eiselstein* case claimed a nickel based compound with the claim term “about 5 to about 15%.” The Federal Circuit explicitly stated that the meaning of the word “about” is dependent on the facts of the case, the nature of the invention, and what the disclosure teaches one of ordinary skill in the art. *See id.* at 1470. In the instant case, to one of ordinary skill in the art, temperature ranges are well-known and understood. Use of the term about does not render the claim indefinite. One of ordinary skill in the art would know that the end points stated for a numerical range would be approximate. Accordingly, Applicants respectfully request reconsideration of the rejection.

B. §112, 1st ¶

Claim 7 stands rejected under 35 USC §112, 1st ¶, because the Examiner contends that the disclosure is not enabling for Applicants Claims. Applicants respectfully request reconsideration of the rejection in light of this argument.

Case law establishes that Applicants’ invention is enabled. The Examiner contends that the specification does not provide a repeatable method for obtaining a temperature sensitive mutant. However, the case law is clear that some experimentation is permissible. For example, under the case of *Flehmig v. Giesa*, the examples provided by applicants enabled the invention for the claims. *See* 13 USPQ2d 1052, 1057 (Bd. of Pat. App. 1989). In the *Flehmig* case, the Board

held that the prior art did enable the claims of that invention. The Board further held that “the mere fact that some experimentation is necessary to determine whether a particular strain of HAV will culture on a particular cell culture is not fatal to enablement when as here the procedures and cultures are routine.” *Id.* Here, the case is much the same. The method can be performed and does disclose Applicants’ invention.

The factual premises of the enablement analysis for biological processes were addressed in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the court explaining that determination of whether the requisite amount of experimentation is undue may include consideration of:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737; 8 USPQ2d at 1404. *See Amgen, Inc. v. Chugai Pharm. Co.*, 727 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (discussing application of the *Wands* factors). In *In re Goodman*, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993) the *Wands* factors were applied to a gene transformation method, the court finding that the method “would have required extensive experimentation that would preclude patentability.” While it is true that it is insufficient to name or describe the desired subject matter, if it cannot be produced without undue experimentation, Applicants have provided the necessary guidance for enablement.

The determination of what level of experimentation is “undue,” so as to render a disclosure non-enabling, is made from the viewpoint of persons experienced in the field of the

invention. *See Enzo Biochem*, 188 F.3d at 1373-74 (discussing evidence of enablement and nonenablement in an unpredictable field of biotechnology). "The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). In *Wands* the court observed that "[t]he test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed" *Id.*, quoting *In re Jackson*, 217 USPQ 804, 817 (Bd. App. 1982). Here, any experimentation is routine, as admitted by the Examiner. Accordingly, Applicants' claimed invention is enabled. Therefore, Applicants respectfully request reconsideration of the rejection, in light of this response.

Applicants are submitting the Declaration of William P. Ramey, II in support of the deposit of biological materials and respectfully request reconsideration of the rejection.

C. §102(b)

Claims 6, 8, and 10-14 stand rejected under 35 U.S.C. § 102 (b) as being anticipated by GB 1,570,732 (hereinafter referred to as the '732 patent). The Examiner contends that the claim limitation is anticipated by the claims in teaching of the '732 patent because the serial passes limitation reads on non-toxic mutagen. Applicants respectfully request reconsideration of the rejection. Further, the Examiner contends that the limitation of 33°C meets the limitation of about 34°C in applicant's claims. Applicants respectfully request reconsideration in light of this

response.

One skilled in the art would understand the limitation of about 34°C as not including 33°C. Accordingly, Applicants respectfully request reconsideration of the rejection in light of this response.

Further, the serial passaging is not claimed in Applicants' invention. The non-toxic form of mutagenesis does not include serial passaging, as is clear from the Specification. One of ordinary skill in the art would recognize that serial passaging is not within the scope of the claims, when read in light of the specification.

D. §103(a) Rejection

Claims 6 and 8-14 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the '732 patent in the article to Sydney. The Examiner contends that the '732 patent teaches a process for reducing an attenuated temperature sensitive equine herpes virus and directs our attention to the claims for support. Further the Examiner contends that the Sydney article teaches that the mutagenic effect of 5-azacytidine. Specifically, the Examiner contends that the effect of incubation of a virus, such as arbo virus, with the mutagen would render a mutation to said virus. The Examiner contends that the only difference is that they did not use equine herpesvirus. In conclusion, the Examiner contends that one of ordinary skill in the art at the time of filing would have been motivated by the above cited art to produce temperature sensitive equine herpesvirus to be utilized in the vaccine production or detection assay. Applicants respectfully request reconsideration of the rejection in light of this response.

It is basic patent law that to establish a prima facie case of obviousness, an Examiner

must show "some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). "The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved." *Kotzab*, 217 F.3d at 1370, 55 USPQ2d at 1317. Here, the elements are not present with any indication for a combination.

In this case, the Examiner has identified elements in the prior art for the basis of the rejection. This is impermissible. *See id.* Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *See In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998); *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984).

Case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing teaching or suggestion or motivation to combine as an essential evidentiary component of an obviousness holding); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of

combination only by showing some objective teaching leading to the combination); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion essential to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 (strict observance of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability. This is the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, the Examiner fell into the hindsight trap.

The Examiner has stated that the skill in the art supplies the necessary combination. However, rarely will the skill in the art component operate to supply missing knowledge or prior art to reach an obviousness judgment. *See W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher."). Skill in the art does not act as a bridge over gaps in substantive presentation of an obviousness case, but instead supplies the primary guarantee of objectivity in the process. *See Ryko Mfg. Co. v. Nu-Star, Inc.*, 950

F.2d 714, 718, 21 USPQ2d 1053, 1057 (Fed. Cir. 1991). Here, there is no suggestion or motivation and the rejection impermissible. Accordingly, Applicants respectfully request reconsideration.

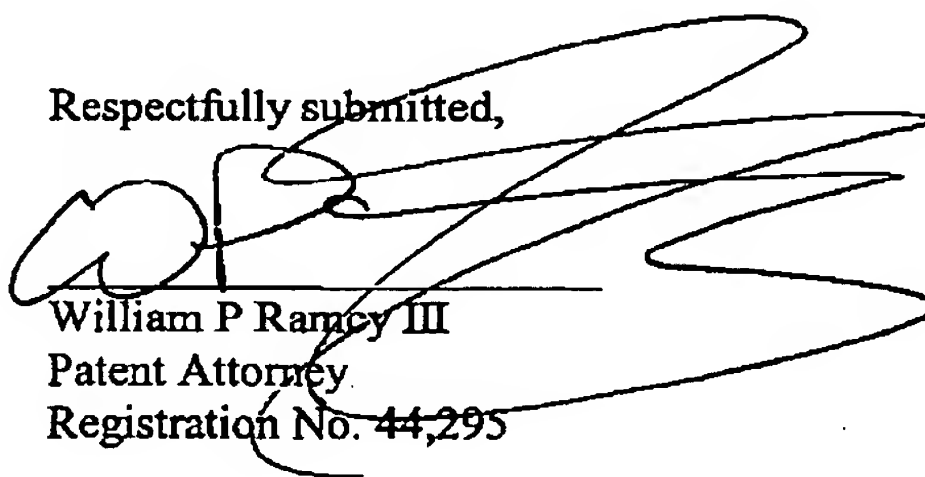
E. Claim 7

Applicants extend their thanks to the Examiner for indicating Claim 7 as allowable. Applicants wish to continue prosecution to seek allowability of the presently elected Claims.

V. Conclusion

The Claims are believed in a condition for allowance and such action is respectfully requested. Applicants further request that the Examiner contact Applicants attorney to facilitate allowance of the Claims and schedule an interview prior to action. Please charge any required fees and credit any credits to deposit account 02-2334. Further, Applicants petition for a one-month extension of time and request the fee for such extension of time be charged to deposit account 02-2334.

Respectfully submitted,



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